

Enclosure D - 510(k) Summary

MAR 17 1997

This summary regarding 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.93.

The Acumed Suture Washer is intended for soft tissue fixation, small bone fixation, and large bone fixation and may be used in conjunction with a 3.5mm or 4.0mm titanium bone screw and suture. This device is not intended for usage in the spine. This washer has a post height of 2.6mm and an outer diameter of 8.0mm. The Extremity Screw is manufactured from a titanium alloy per ASTM F 136 and is provided sterile. Sterility is achieved by a minimum of 2.5 Mrads gamma radiation. Verification of sterility is performed with the AAMI - Method 1. Sterility assurance level is 10^{-6} . We make no claims as to the pyrogenicity of this product. Packaging and labeling information have already been provided.

The Acumed Suture Washer is similar to the Linvatec Spiked Washer in material, design, and intended usage and is expected to perform as well as similar devices.